

PCT COOPERATION TREATY

PCT

From the INTERNATIONAL BUREAU

NOTIFICATION OF THE RECORDING
OF A CHANGE(PCT Rule 92bis.1 and
Administrative Instructions, Section 422)

To:

AWAPATENT AB
Box 45086
S-104 30 Stockholm
SUÈDE

Date of mailing (day/month/year) 21 June 2001 (21.06.01)	IMPORTANT NOTIFICATION
Applicant's or agent's file reference PC2008983	
International application No. PCT/SE00/01945	International filing date (day/month/year) 06 October 2000 (06.10.00)

1. The following indications appeared on record concerning:		
<input checked="" type="checkbox"/> the applicant	<input type="checkbox"/> the inventor	<input type="checkbox"/> the agent <input type="checkbox"/> the common representative
Name and Address ASTRAZENECA AB S-151 85 Södertälje Sweden	State of Nationality SE	State of Residence SE
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	
2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:		
<input checked="" type="checkbox"/> the person	<input type="checkbox"/> the name	<input type="checkbox"/> the address <input type="checkbox"/> the nationality <input type="checkbox"/> the residence
Name and Address ASTRA TECH AB Aminogatan 1 S-431 21 Mölndal Sweden	State of Nationality SE	State of Residence SE
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	
3. Further observations, if necessary: The applicant indicated in Box 1 has assigned his rights for all designated States except US to the applicant indicated in Box 2.		
4. A copy of this notification has been sent to:		
<input checked="" type="checkbox"/> the receiving Office	<input checked="" type="checkbox"/> the designated Offices concerned	
<input type="checkbox"/> the International Searching Authority	<input type="checkbox"/> the elected Offices concerned	
<input type="checkbox"/> the International Preliminary Examining Authority	<input type="checkbox"/> other:	

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer F. Baechler
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

PCT COOPERATION TREATY

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NOTIFICATION RELATING TO PRIORITY CLAIM

(PCT Rules 26bis.1 and 26bis.2 and
Administrative Instructions, Sections 402 and 409)

From the INTERNATIONAL BUREAU

To:

AWAPATENT AB
Box 45086
S-104 30 Stockholm
SUÈDE

Date of mailing (day/month/year) 06 February 2001 (06.02.01)	
Applicant's or agent's file reference PC2008983	IMPORTANT NOTIFICATION
International application No. PCT/SE00/01945	International filing date (day/month/year) 06 October 2000 (06.10.00)
Applicant ASTRAZENECA AB et al	

The applicant is hereby notified of the following in respect of the priority claim(s) made in the international application.

1. ☐ **Correction of priority claim.** In accordance with the applicant's notice received on: ,
the following priority claim has been corrected to read as follows:
 - ☐ even though the indication of the number of the earlier application is missing.
 - ☐ even though the following indication in the priority claim is not the same as the corresponding indication appearing in the priority document:
2. ☒ **Addition of priority claim.** In accordance with the applicant's notice received on: 22 January 2001 (22.01.01),
the following priority claim has been added:

SE 06 October 1999 (06.10.99) 9903607-1

 - ☐ even though the indication of the number of the earlier application is missing.
 - ☐ even though the following indication in the priority claim is not the same as the corresponding indication appearing in the priority document:
3. ☐ As a result of the correction and/or addition of (a) priority claim(s) under items 1 and/or 2, the (earliest) priority date is:
4. ☐ **Priority claim considered not to have been made.**
 - ☐ The applicant failed to respond to the invitation under Rule 26bis.2(a) (Form PCT/IB/316) within the prescribed time limit.
 - ☐ The applicant's notice was received after the expiration of the prescribed time limit under Rule 26bis.1(a).
 - ☐ The applicant's notice failed to correct the priority claim so as to comply with the requirements of Rule 4.10.

The applicant may, before the technical preparations for international publication have been completed and subject to the payment of a fee, request the International Bureau to publish, together with the international application, information concerning the priority claim. See Rule 26bis.2(c) and the PCT Applicant's Guide, Volume I, Annex B2(II).
5. ☐ In case where multiple priorities have been claimed, the above item(s) relate to the following priority claim(s):
6. A copy of this notification has been sent to the receiving Office and
 - ☒ to the International Searching Authority (where the international search report has not yet been issued).
 - ☒ the designated Offices (which have already been notified of the receipt of the record copy).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. (41-22) 740.14.35	Authorized officer N. Lindner Telephone No. (41-22) 338.83.38
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PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Commissioner
US Department of Commerce
United States Patent and Trademark
Office, PCT
2011 South Clark Place Room
CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE
in its capacity as elected Office

Date of mailing (day/month/year) 28 June 2001 (28.06.01)	
International application No. PCT/SE00/01945	Applicant's or agent's file reference PC2008983
International filing date (day/month/year) 06 October 2000 (06.10.00)	Priority date (day/month/year) 06 October 1999 (06.10.99)
Applicant ALBREKTSSON, Tomas et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:
25 April 2001 (25.04.01)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer <p style="text-align: center;">Nestor Santesso</p> Telephone No.: (41-22) 338.83.38
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PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PC-2008983	<div style="display: flex; justify-content: space-between;"> <div> FOR FURTHER ACTION </div> <div> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) </div> </div>	
International application No. PCT/SE00/01945	International filing date (<i>day/month/year</i>) 06.10.2000	Priority date (<i>day/month/year</i>) 06.10.1999
International Patent Classification (IPC) or national classification and IPC ₇ A 61 F 2/32		
Applicant ASTRA TECH AB et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 25.04.2001	Date of completion of this report 10.01.2002
Name and mailing address of the IPEA/SE Patent- och registreringsverket Box 5055 S-102 42 STOCKHOLM Facsimile No. 08-667 72 88	Authorized officer Leif Brander/Els Telephone No. 08-782 25 00

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/SE00/01945

I. Basis of the report

1. With regard to the elements of the international application:*

- ☒ the international application as originally filed
- ☐ the description:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☐ the claims:
 pages _____, as originally filed
 pages _____, as amended (together with any statement) under article 19
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☐ the drawings:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☐ the sequence listing part of the description:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheet/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2 (c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item I and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/SE00/01945

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	<u>1-37</u>	YES
	Claims		NO
Inventive step (IS)	Claims	<u>1-37</u>	YES
	Claims		NO
Industrial applicability (IA)	Claims	<u>1-37</u>	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

The invention relates to a femur fixture for a hip-joint prosthesis.

Documents cited in the International Search Report:

1. WO 97025939 A1
2. EP 05767349 A1
3. US 3996625 A
4. US 4015559 A

The cited document WO 9725939 A1 shows an intraosseous anchoring structure according to claim 1 with a proximal end, a distal end and a proximal cylindrical section (8) having a screw thread profile thereon and extending towards the distal end from the proximal section (figure 2). However, none of the documents disclose a frusto-conical proximal section at the proximal end of the structure and this arrangement is not obvious to a person skilled in the art.

According to the arguments stated above, the fixture and the set of fixtures claimed in claims 1-37 is novel, considered to involve an inventive step and have industrial applicability.

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTICE INFORMING THE APPLICANT OF THE COMMUNICATION OF THE INTERNATIONAL APPLICATION TO THE DESIGNATED OFFICES

(PCT Rule 47.1(c), first sentence)

To:

AWAPATENT AB
Box 45086
S-104 30 Stockholm
SUÈDE

RECEIVED

2001-04-20

AWAPATENT, S&VT

Date of mailing (day/month/year) 12 April 2001 (12.04.01)		IMPORTANT NOTICE	
Applicant's or agent's file reference PC2008983			
International application No. PCT/SE00/01945	International filing date (day/month/year) 06 October 2000 (06.10.00)	Priority date (day/month/year) 06 October 1999 (06.10.99)	
Applicant ASTRAZENECA AB et al			

1. Notice is hereby given that the International Bureau has communicated, as provided in Article 20, the international application to the following designated Offices on the date indicated above as the date of mailing of this Notice:

AU,KP,KR,US

In accordance with Rule 47.1(c), third sentence, those Offices will accept the present Notice as conclusive evidence that the communication of the international application has duly taken place on the date of mailing indicated above and no copy of the international application is required to be furnished by the applicant to the designated Office(s).

2. The following designated Offices have waived the requirement for such a communication at this time:

AE,AG,AL,AM,AP,AT,AZ,BA,BB,BG,BR,BY,BZ,CA,CH,CN,CR,CU,CZ,DE,DK,DM,DZ,EA,EE,EP,ES,
FI,GB,GD,GE,GH,GM,HR,HU,ID,IL,IN,IS,JP,KE,KG,KZ,LC,LK,LR,LS,LT,LU,LV,MA,MD,MG,MK,
MN,MW,MX,MZ,NO,NZ,OA,PL,PT,RO,RU,SD,SE,SG,SI,SK,SL,TJ,TM,TR,TT,TZ,UA,UG,UZ,VN,YU,
The communication will be made to those Offices only upon their request. Furthermore, those Offices do not require the applicant to furnish a copy of the international application (Rule 49.1(a-bis)).

3. Enclosed with this Notice is a copy of the international application as published by the International Bureau on
12 April 2001 (12.04.01) under No. WO 01/24738

REMINDER REGARDING CHAPTER II (Article 31(2)(a) and Rule 54.2)

If the applicant wishes to postpone entry into the national phase until 30 months (or later in some Offices) from the priority date, a demand for international preliminary examination must be filed with the competent International Preliminary Examining Authority before the expiration of 19 months from the priority date.

It is the applicant's sole responsibility to monitor the 19-month time limit.

Note that only an applicant who is a national or resident of a PCT Contracting State which is bound by Chapter II has the right to file a demand for international preliminary examination.

REMINDER REGARDING ENTRY INTO THE NATIONAL PHASE (Article 22 or 39(1))

If the applicant wishes to proceed with the international application in the national phase, he must, within 20 months or 30 months, or later in some Offices, perform the acts referred to therein before each designated or elected Office.

For further important information on the time limits and acts to be performed for entering the national phase, see the Annex to Form PCT/IB/301 (Notification of Receipt of Record Copy) and Volume II of the PCT Applicant's Guide.

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer J. Zahra
Facsimile No. (41-22) 740.14.35	Telephone No. (41-22) 338.83.38

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
12 April 2001 (12.04.2001)

PCT

(10) International Publication Number
WO 01/24738 A1

(51) International Patent Classification⁷: A61F 2/32

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(22) International Filing Date: 6 October 2000 (06.10.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data: 9903612-1 6 October 1999 (06.10.1999) SE
9903607-1 6 October 1999 (06.10.1999) SE

(71) Applicant (for all designated States except US): AS-TRAZENECA AB [SE/SE]; S-151 85 Södertälje (SE).

(72) Inventors; and

(75) Inventors/Applicants (for US only): ALBREKTSSON, Tomas [SE/SE]; Antilopgatan 6, S-431 38 Mölndal (SE). CARLSSON, Lars [SE/SE]; Ortopeden, Sahlgrenska

Sjukhuset, S-413 45 Göteborg (SE). JACOBSSON, Magnus [SE/SE]; Astra Tech AB, Box 14, S-431 21 Mölndal (SE). MACDONALD, Warren [SE/SE]; Astra Tech AB, Box 14, S-431 21 Mölndal (SE). WENNERBERG, Stig [SE/SE]; Villa Holma, P1 6266, S-424 57 Gunnarby (SE).

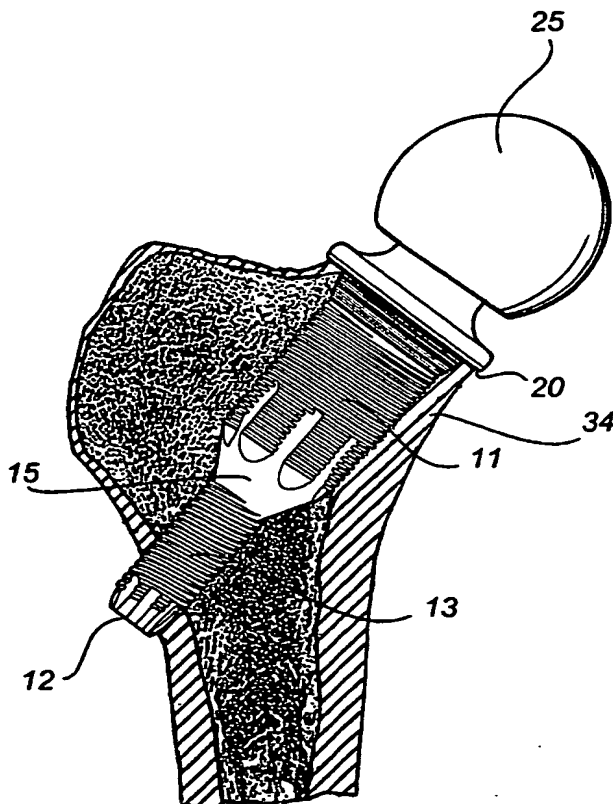
(74) Agent: AWAPATENT AB; Box 45086, S-104 30 Stockholm (SE).

(81) Designated States (national): AE, AG, AL, AM, AT, AT (utility model), AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, CZ (utility model), DE, DE (utility model), DK, DK (utility model), DM, DZ, EE, EE (utility model), ES, FI, FI (utility model), GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KR (utility model), KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (utility model), SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian

[Continued on next page]

(54) Title: FEMUR FIXTURE AND SET OF FEMUR FIXTURES



(57) Abstract: A femur fixture (1) for a hip-joint prosthesis comprising an intraosseous anchoring structure (3) of a generally circular cross-section for screwing laterally into a complementary bore drilled laterally into the neck of a femur after resection of the femur head to an anchored position. The intraosseous anchoring structure (3) has a proximal end, a distal end, a relatively short frusto-conical proximal section (18) at the proximal end, and a proximal cylindrical section (11) having a screw thread profile thereon. The proximal cylindrical section (11) extends from the frusto-conical proximal section (18) towards the distal end of the anchoring structure (3). The frusto-conical proximal section (18) and the proximal cylindrical section (11) each being dimensioned so as to bear against the cortex of the femur neck when the intraosseous anchoring structure (3) is in the anchored position. The invention also relates to a set of such femur fixtures, wherein the frusto-conical proximal section (18) and the proximal cylindrical section (11) of each fixture (1) in the set have different dimensions, whereby the fixture in the set having the frusto-conical proximal section (18) and the proximal cylindrical section (11) of correct size for abutting the cortex of the femur neck of a particular patient can be selected for use in that patient.

WO 01/24738 A1



patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

— *Before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments.*

Published:

— *With international search report.*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

FEMUR FIXTURE AND SET OF FEMUR FIXTURESField of the Invention

The present invention relates to a femur fixture for a hip-joint prosthesis comprising an intraosseous anchoring structure of a generally circular cross-section adapted for screwing laterally into a complementary bore drilled laterally into the neck of a femur after resection of the femur head to an anchored position. The invention also relates to a set of such femur fixtures.

10 Background of the Invention

A femur fixture of the aforementioned type is disclosed in Applicant's prior International patent application publication WO93/16663. In this femur fixture the intraosseous structure has a screw threaded cylindrical section at the proximal end. The use of a cylindrical proximal section in the intraosseous structure of the femur fixture of WO93/16663 enables the threads thereon to engage with the cortex of the femur neck and increase the fixation strength of the femur fixture in the femur. However, the threads at the terminal proximal section of the cylindrical section do not register in the medial cortex of the femur neck at the resected surface. This is due to the cortex of the femur neck flaring outwardly adjacent the resected surface.

25 This lack of loading of the cortex at the resected surface of the femur by the intraosseous anchoring structure of the femur fixture can lead to bone resorption at the resected surface. This situation is not able to be simply addressed by increasing the diameter of the cylindrical proximal section of the intraosseous anchoring structure of the WO93/16663 femur fixture since it would result in the threads of the cylindrical proximal section puncturing the cortex in the body of the femur neck or

being dangerously close to puncturing the cortex due to the trumpet-like shape of the cortex in the femur neck.

Summary of the Invention

5 Thus, the object of the present invention is to provide an improved femur fixture where the above mentioned drawback is addressed.

 This and other objects are achieved according to the present invention by providing a femur fixture having the
10 features defined in the independent claim. Preferred embodiments are defined in the dependent claims.

 According to the present invention there is provided a femur fixture for a hip-joint prosthesis, comprising an
15 intraosseous anchoring structure of a generally circular cross-section for screwing laterally into a complementary bore drilled laterally into the neck of a femur after resection of the femur head to an anchored position. The intraosseous anchoring structure has a proximal end, a distal end, a relatively short frusto-conical proximal
20 section at the proximal end, and a proximal cylindrical section having a screw thread profile thereon and extending towards the distal end from the frusto-conical proximal section, the frusto-conical proximal section and the proximal cylindrical section each being dimensioned so as
25 to bear against the cortex of the femur neck when the intraosseous anchoring structure is in the anchored position.

 Thus, the present invention is based on the advantageous idea of providing a femur fixture of the above-
30 mentioned type with a relatively short frusto-conical proximal section at the proximal end of the intraosseous anchoring structure.

 The provision of a relatively short frusto-conical proximal section at the proximal end of the intraosseous
35 anchoring structure thus loads the cortex of the femur neck adjacent the resected surface and the proximal cylindrical section loads the cortex in the body of the fe-

mur neck. Thereby, an improved anchorage of the femur fixture in the femur of the patient can be obtained.

The frusto-conical section preferably has a flank angle in the range of 8-15°, preferably in the range 10-13°, even more preferably approximately 12°.

According to preferred embodiments of the invention the frusto-conical section has an axial extent in the range of 5-10 mm. Preferably, the axial extent is approximately 8 mm.

Advantageously, the proximal end of the frusto-conical proximal section has a diameter in the range of 18-30 mm.

Advantageously, the distal end of the frusto-conical proximal section, i.e. the end interfacing the proximal cylindrical section, has essentially the same diameter as the proximal cylindrical section. Thus, there will be no sharp edges in the transition area between the frusto-conical proximal section and the proximal cylindrical section that could induce undesired stresses.

According to preferred embodiments of the invention the frusto-conical section has at least partly a roughened surface. This improves the integration of the frusto-conical section with the cortex (termed "osseointegration" in the art). The roughening may be achieved by grit blasting, etching or machining, or by a combination of one or more of these roughening techniques.

Alternatively or additionally, the frusto-conical proximal section could be provided with a circumferentially oriented roughness, preferably machined. Such circumferentially oriented roughness could for instance be provided in the form of grooves, beads, tracks, or screw threads. The provision of such a circumferentially oriented roughness would improve the short term anchorage capacity of the intraosseous anchoring structure due to the engagement of the circumferentially oriented roughness with the cortex of the femur neck adjacent the re-

sected surface, as well as even further promote the osseointegration process.

According to an embodiment of the invention, the frusto-conical proximal section is provided with a screw thread profile similar to that of the proximal cylindrical section.

According to preferred embodiments of the invention, the frusto-conical proximal section has a screw thread profile of a height less than the screw thread profile of the proximal cylindrical section. Preferably, the height of the screw thread profile on the frusto-conical proximal section is no greater than 0.3 mm (microthreads), more preferably in the range 0.1-0.25 mm, and even more preferably approximately 0.2 mm.

According to another embodiment of the invention, the frusto-conical proximal section is provided with circumferential beads of a height less than the screw thread profile of the proximal cylindrical section. Preferably, the height of the beads is no greater than 0.3 mm, more preferably in the range 0.1-0.25 mm, and even more preferably approximately 0.2 mm.

According to preferred embodiments of the invention, the intraosseous anchoring structure is dimensioned such that the distal end of the anchoring structure projects through the lateral cortex of the femur when the intraosseous anchoring structure is in the anchored position. This arrangement, together with the inventive features of having a frusto-conical proximal section at the proximal end of the anchoring structure, provides a strong anchorage of the anchoring structure in the cortical bone tissue of the femur.

Advantageously, the intraosseous anchoring structure further has a screw threaded, distal cylindrical section, which extends from the distal end of the intraosseous anchoring structure towards the proximal cylindrical section. The diameter of the distal cylindrical section is less than the diameter of said proximal cylindrical section.

tion. Preferably, the screw thread profiles of the proximal and distal cylindrical sections are essentially the same.

According to an embodiment of the invention, the intraosseous anchoring structure further comprises a tapered connecting section provided between the proximal and distal cylindrical sections. This tapered connecting section interconnects the proximal and distal cylindrical sections and, preferably, has a frusto-conical shape which at one end has a base diameter essentially equal to the diameter of said proximal cylindrical section, and at the other end has a top diameter essentially equal to the diameter of said distal cylindrical section.

The provision of a tapered connecting section would radically reduce any stresses that might be induced by a sharp, step-wise transition between the cylindrical sections of differing diameters. Further, insertion of the fixture would be facilitated, the short and long term stability of the fixture would be improved, as well as the process of osseointegration between the fixture and the surrounding bone tissue.

Advantageously, the proximal end of the tapered connecting section has essentially the same diameter as the proximal cylindrical section. Likewise, the distal end of the tapered connecting section advantageously has essentially the same diameter as the distal cylindrical section.

According to preferred embodiments of the invention, the diameter of the first cylindrical section is adapted to the actual size and shape of the femur of the particular patient for whom the femur fixture is intended. Thus, the diameter of the first cylindrical section can vary considerably. However, the diameter of the second cylindrical section is preferably dimensioned to be within a short, limited range. Thus, the flank angle of the connecting section may vary in dependence of the actual dimensions of the first and second cylindrical sections.

Preferably, the flank angle can be varied in the range of 10°-50°, and more preferably in the range of 20°-40°.

Preferably, the tapered connecting section is at least partly provided with a roughened surface. This would even further promote the osseointegration process at the transition area between the cylindrical sections. The roughened surface could be achieved through blasting, preferably grit-blasting, etching, or the like. Alternatively or additionally, the surface of the tapered proximal section is provided with a circumferentially oriented roughness, for instance in the form of circumferential beads or screw threads. The height of the beads or screw threads is preferably no greater than 0.3 mm, more preferably in the range of 0.1-0.25 mm, and even more preferably approximately 0.2 mm.

According to an embodiment of the invention as hereinafter described, the tapered connecting section is at least in part provided with one or more self-tapping cutting recesses.

According to preferred embodiments of the present invention, femur fixture further comprises a head section. The head section is provided with a collar abutting the tapered proximal section, which collar delimits the insertion of the femur fixture into bone tissue. Preferably, the surface of the collar facing the proximal section is inclined inwardly so as to mate with a resected bone tissue surface that has been given a correspondingly inclined shape. Preferably, the angle of inclination is within the range of 10°-20°, preferably approximately 15°. Alternatively, the surface of the collar facing the proximal section is given a concave shape, so as to mate with a convex bone tissue surface. Thereby, an improved contact between the femur fixture and the bone surface can be obtained.

Preferably, said collar surface is provided with radially spaced circular beads or grooves for increasing the stability of the inserted femur fixture and promote

the osseointegration between the femur fixture and the bone tissue. Preferably, these beads have a height in the range of 0.1-0.5 mm, preferably in the range of 0.2-0.4 mm, and even more preferably approximately 0.3 mm.

5 According to a preferred embodiment the present invention there is further provided a set of femur fixtures according to the invention with the frusto-conical proximal section and the proximal cylindrical section of each fixture in the set having different dimensions, whereby
10 the fixture in the set having the frusto-conical and cylindrical sections of correct size for abutting the cortex of the femur neck of a patient can be selected for use in that patient.

 According to a preferred embodiment of the invention,
15 there is further provided a set where the frusto-conical proximal section and the proximal cylindrical section of each fixture in the set have different dimensions, while the dimension of the distal cylindrical section is essentially the same for all fixtures in the set.
20 Thereby, the fixture in the set having the frusto-conical and cylindrical sections of correct size for abutting the cortex of the femur neck of a particular patient can be selected for use in that patient.

 An exemplary embodiment of the invention will now be
25 described with reference to the accompanying Figures of drawings.

Brief Description of the Accompanying Figures of Drawings

 Fig. 1 is a perspective view of a femur fixture for
30 a hip-joint prosthesis in accordance with an embodiment of the invention,

 Fig. 2 is an opposite perspective view of the femur fixture shown in Fig. 1,

 Fig. 3 is a longitudinal side view of the femur fixture,
35

 Fig. 4 is a longitudinal sectional view of the femur fixture,

Fig. 5 is an enlarged fragmentary sectional view showing the tapered proximal section and the head of the femur fixture,

Fig. 6 is a bottom view of the femur fixture,

5 Fig. 7 is a fragmentary sectional view of the collum of the human femur, with a cavity formed therein for reception of the femur fixture, and

Fig. 8 is a fragmentary sectional view of the collum of the human femur, with the femur fixture inserted
10 therein.

Description of Exemplary Embodiment

With reference to Figs 1-8, there is shown an integrally formed femur fixture 1 for a hip-joint prosthesis preferably made from commercially pure titanium and consisting of (i) an intraosseous anchoring section 3 of circular cross-section, and (ii) a head section 5. The anchoring section 3 is intended for insertion laterally into a cavity 30 of complementary profile (Fig. 7), said
15 cavity 30 being drilled into the neck of a femur through a resected section 33 made by resection of the head of the femur. The head section 5 of the fixture, which will protrude from the resected section 33 when the intraosseous anchoring section 3 is located in the cavity 30
20 (Fig. 8), is arranged for supporting a ball 25 of the hip-joint prosthesis which interacts with the anatomical acetabular cavity or an acetabular part of the hip-joint prosthesis where a total hip-joint prosthesis is required.

30 As can be seen in Figs 1-3, the intraosseous anchoring section 3 has proximal and distal cylindrical sections 11, 13 of different outer diameter, with the diameter of the proximal cylindrical section 11 being greater than that of the distal cylindrical section 13. The intraosseous anchoring section 3 further has a tapered terminal distal section 12, contiguous with the distal cylindrical section 13, a frusto-conical connecting section
35

15 connecting the proximal cylindrical section 11 to the distal cylindrical section 13, and a frusto-conical proximal section 18 connecting the proximal cylindrical section 11 to the head section 5.

5 The proximal cylindrical section 11 presents a screw-threaded outer surface for screwing into an outer bone cavity section 32 of said cavity. The distal cylindrical section 13 also presents a screw-threaded outer surface, for screwing into a narrow drilled hole 31,
10 which is coaxial with said outer cavity section 32. The screw-threads of the proximal cylindrical section 11 have the same pitch and height as those of the distal cylindrical section 13.

15 The major diameters of the screw threads on the proximal and distal cylindrical sections 11, 13 are sized to be greater than the inner diameter of complementary cylindrical sections of the outer cavity section 32 and the drilled hole 31 provided in the cavity 30 of the femur neck (See Fig. 7). Accordingly, the intraosseous anchoring section 3 is able to be anchored in the cavity 30
20 by screwing of the femur fixture 1 into the cavity 30, with the screw threads on the proximal and distal cylindrical sections 11, 13 threading into the bone tissue in the boundary wall of the cavity 30.

25 As seen in Fig. 8, the diameter of the proximal cylindrical section 11 is in fact sized such that the threads thereon register in the peripheral layer of cortical bone 34 in the femur neck, as outlined in WO93/16663 and WO97/25939. The threads on the proximal
30 cylindrical section 11 are thus secured in the stronger cortical bone 34 as opposed to the spongier cancellous bone 35, thereby giving the femur fixture 1 greater fixation in the femur neck. Due to the fact that the femur dimensions can vary from patient to patient, the diameter
35 of the proximal cylindrical section can vary in the range from approximately 16-26 mm (cf. Figs 3 and 8).

As illustrated in Fig. 8, the axial length of the intraosseous anchoring section 3 is such that in the anchored position of the intraosseous anchoring section 3, the distal end 12 thereof projects through the lateral cortex 34 of the femur.

With reference to Figs 3-5, the frusto-conical proximal section 18 also has threads thereon. The height of these threads is 0.2 mm (so-called microthreads) which is less than that of the threads on the proximal and distal cylindrical sections 11, 13. Further, the frusto-conical proximal section 18 is sized so that the microthreads engage with the cortex 34 of the femur neck at the resected surface. In the embodiment described herein, the frusto-conical terminal proximal section 18 has a flank angle of approximately 12° , and an axial extent of approximately 8 mm.

The distal diameter of the proximal section 18 is adapted to the diameter of the neighbouring proximal cylindrical section 11, such that there are no sharp edges in the transition area between the frusto-conical proximal section 18 and the proximal cylindrical section 11. Consequently, the proximal diameter of the frusto-conical proximal section 18 is in the range of approximately 20-30 mm.

The diameter of the distal cylindrical section 13 does not have to be varied in dependence of the femur dimensions of the patient. The diameter of the distal cylindrical section 13 is approximately 11 mm, or within the range of 10-12 mm.

The frusto-conical connecting section 15 interconnects the proximal and distal cylindrical sections 11, 13 to one another. In this embodiment, the diameters at the respective end of the connecting section 15 correspond to the diameters of the proximal and distal cylindrical sections 11, 13, respectively. In other words, the distal end of the connecting section 15 has essentially the same diameter as the distal cylindrical section 13, and the

proximal end of the connecting section 15 has essentially the same diameter as the proximal cylindrical section 11.

As a result of the fact that the diameter of the proximal cylindrical section 11 can be varied between
5 different femur fixtures, while the diameter of the distal cylindrical section 13 is not varied, the dimensions of the connecting section will be varied in accordance with the varying difference in diameter between the proximal cylindrical section 11 and the distal cylindrical section 13. Since the axial extent of the connecting
10 section is kept relatively short, i.e. within the range of approximately 7.5-10.5 mm, the flank angle of the connecting section can vary from approximately 20° for the narrowest fixture alternative, up to approximately 37°
15 for the widest fixture alternative.

In the herein described embodiment of the invention, the surface of the frusto-conical connecting section 15 is provided with a grit-blasted surface for promoting the osseointegration between the surface and the surrounding
20 cancellous bone tissue. The surface could also, or alternatively, be provided with a screw thread profile for promoting said osseointegration and improve the anchorage of the femur fixture 1. As a further alternative, the frusto-conical connecting section 15 may be left smooth,
25 even polished.

As can be seen in figs 2 and 3, bridging the boundary between the proximal cylindrical section 11 and the frusto-conical connecting section 15 are a series of equi-spaced, circumferentially-arranged, sharp-edged cutting recesses or notches 14 for self-tapping into a pre-cut outer bone cavity section 32. The cutting recesses 14
30 each communicate with a channel 16 in the proximal cylindrical section 11 for autologous transplantation of the bone cut by the cutting recesses 14 as the femur fixture 1 is screwed into the bore in the femur neck, as detailed
35 in WO97/25939.

Further, bridging the boundary between the distal cylindrical section 13 and the tapered terminal distal section 12 are also a series of short, sharp-edged circumferentially-arranged cutting recesses 17 for the distal cylindrical section 13 to be self-tapped into said drilled, relatively narrow hole 31.

With reference to Figs 1, 7 and 8, the head section 5 of the femur fixture 1 has a collar section 20 and a tapered mounting section 23 for the ball component 25 of the hip-joint prosthesis to be mounted on. The mounting section 23 is provided with a recess 24 for reception of the ball component 25. The collar section 20 delimits the insertion of the intraosseous anchoring section 3 into the bore in the femur neck by abutting with the resected femur section 33 adjacent the opening to the cavity 30. As can be seen in Fig. 5, the distal surface 21 (Fig. 5) is inclined inwardly for mating with a correspondingly inclined bone surface the resected femur section 33 (Fig. 7). The angle of inclination in the embodiment herein described is approximately 15°. Further, as seen in Fig. 6, for improved anchorage and osseointegration, the distal surface 21 of the collar section 20 is provided with radially spaced, circumferential beads 22, said beads having a height of approximately 0.3 mm.

The surgical procedures described in WO93/16663 and WO97/25939 for implanting the femur fixtures disclosed therein can also be adapted for implantation of the femur fixture 1 and as such are incorporated herein by reference.

The anchorage of the femur fixture 1 is primarily reliant on the registration of the threads in the bone of the femur, principally the registration of the threads on the proximal cylindrical section 11 in the cortex 34 of the femur neck and the registration of the threads on the distal cylindrical section 13 in the lateral cortex 34 of the femur. This is in distinction to femur fixtures which

rely on a thrust plate mechanism for their fixation, for example as in GB-A-2033755.

The femur fixture 1 herein described with reference to the accompanying figures can be varied in numerous ways within the scope of the invention. For instance, the femur fixture 1 could be in the form of an assembly in which the component parts are assembled (i) for insertion thereof laterally into the bore as a one-piece structure, as disclosed in W093/16663, or (ii) by connecting the parts together in the bore, as disclosed in W093/01769. The femur fixture 1 could also be made from any biocompatible material of strength sufficient to withstand the loads imposed upon it in situ.

It will be appreciated that the invention has been described with reference to an exemplary embodiment and that the invention can be varied in many different ways within the scope of the appended claims. For instance, the implant is not confined to use as a femur fixture for a hip-joint prosthesis. As an example, the implant could take the form of a bone fixation screw. It will further be appreciated that the use in the appended claims of reference numerals from the Figures of drawings is for the purposes of illustration and not to be construed as having a limiting effect on the claims.

CLAIMS

1. A femur fixture (1) for a hip-joint prosthesis, comprising an intraosseous anchoring structure (3) of a generally circular cross-section for screwing laterally into a complementary bore drilled laterally into the neck of a femur after resection of the femur head to an anchored position, the intraosseous anchoring structure (3) having a proximal end, a distal end, a relatively short frusto-conical proximal section (18) at the proximal end, and a proximal cylindrical section (11) having a screw thread profile thereon and extending towards the distal end from the frusto-conical proximal section (18), the frusto-conical proximal section (18) and the proximal cylindrical section (11) each being dimensioned so as to bear against the cortex of the femur neck when the intraosseous anchoring structure (3) is in the anchored position.

2. The femur fixture (1) as claimed in claim 1, wherein the intraosseous anchoring structure (3) is so dimensioned that its distal end projects through the lateral cortex (34) of the femur when the intraosseous anchoring structure (3) is in the anchored position.

3. The femur fixture (1) as claimed in claim 1 or 2, wherein the intraosseous anchoring structure (3) further has a distal cylindrical section (13) having a screw thread profile thereon and extending towards the proximal cylindrical section (11) from the distal end of the intraosseous anchoring structure (3), the diameter of said distal cylindrical section (13) being less than the diameter of said proximal cylindrical section (11).

4. The femur fixture (1) as claimed in claim 3, wherein the screw thread profiles of said proximal and distal cylindrical sections (11, 13) are essentially the same.

5. The femur fixture (1) as claimed in claim 3 or 4, wherein said intraosseous anchoring structure (3) further

comprises a tapered connecting section (15) provided between and interconnecting said proximal and distal cylindrical sections (11, 13).

6. The femur fixture (1) as claimed in claim 5, wherein said connecting section (15) has a frusto-conical shape which at one end has a base diameter essentially equal to the diameter of said proximal cylindrical section (11), and at the other end has a top diameter essentially equal to the diameter of said distal cylindrical section (13).

7. The femur fixture (1) as claimed in claim 5 or 6, wherein said connecting section (15) has a flank angle in the range of 15° - 45° , preferably in the range of 20° - 40° .

8. The femur fixture (1) as claimed in any one of claims 5-7, wherein said connecting section (15) is at least partly provided with a blasted surface, preferably a grit-blasted surface.

9. The femur fixture (1) as claimed in any one of claims 5-8, wherein said connecting section (15) is at least partly provided with a circumferentially oriented roughness, preferably in the form of circumferential beads or screw threads.

10. The femur fixture (1) as claimed in claim 9, wherein said circumferentially oriented roughness has a height less than that of the screw thread profiles of said proximal and distal cylindrical sections (11, 13).

11. The femur fixture (1) as claimed in claim 9 or 10, wherein the height of said circumferentially oriented roughness is no greater than 0.3 mm, preferably in the range of 0.1-0.25 mm, and even more preferably approximately 0.2 mm.

12. The femur fixture (1) as claimed in any one of claims 5-11, wherein said connecting section (15) is at least partly provided with a smooth surface.

13. The femur fixture (1) as claimed in any one of claims 5-7, wherein the entire surface of said connecting section (15) is smooth.

14. The femur fixture (1) as claimed in any one of claims 5-13, wherein one or more self-tapping cutting recesses (14) are provided at least in part on said connecting section (15).

5 15. The femur fixture (1) as claimed in any one of the preceding claims, wherein said frusto-conical proximal section (18) at an end thereof interfacing said proximal cylindrical section (11) presents a diameter essentially equal to the diameter of said proximal cylindrical section (11).

10 16. The femur fixture as claimed in any one of the preceding claims, wherein said frusto-conical proximal section (18) has a flank angle in the range of 8-15°, preferably in the range of 10-13°, and even more preferably approximately 12°.

15 17. The femur fixture (1) as claimed in any one of the preceding claims, wherein the frusto-conical proximal section (18) has an axial extent in the range of 5-10 mm, preferably approximately 8 mm.

20 18. The femur fixture (1) as claimed in any one of the preceding claims, wherein the frusto-conical proximal section (18) has a proximal diameter in the range of 18-30 mm.

25 19. The femur fixture (1) as claimed in any one of the preceding claims, wherein the frusto-conical proximal section (18) is at least partly provided with a roughened surface.

30 20. The femur fixture (1) as claimed in claim 19, wherein said roughened surface is at least partly a blasted surface, preferably a grit-blasted surface.

21. The femur fixture (1) as claimed in claim 19 or 20, wherein said roughened surface is at least partly provided with a circumferentially oriented roughness.

35 22. The femur fixture (1) as claimed in claim 21, wherein said circumferentially oriented roughness is in the shape of a screw thread profile.

23. The femur fixture (1) as claimed in claim 22, wherein the screw thread profile of said frusto-conical proximal section (18) differs from the screw thread profiles of said proximal cylindrical section (11).

5 24. The femur fixture (1) as claimed in claim 23, wherein the screw thread profile of said frusto-conical proximal section (18) has a height less than the screw thread profile of said proximal cylindrical section (11).

10 25. The femur fixture (1) as claimed in any one of claims 22-24, wherein the height of the screw thread profile on the frusto-conical proximal section (18) is no greater than 0.3 mm, preferably in the range of 0.1-0.25 mm, and even more preferably approximately 0.2 mm.

15 26. The femur fixture (1) as claimed in any one of claims 22-25, wherein the screw thread profile on the frusto-conical proximal section (18) is formed by the turns of one or more screw threads.

20 27. The femur fixture (1) as claimed in claim 21, wherein said circumferentially oriented roughness is in the form of circumferential beads.

28. The femur fixture (1) as claimed in claim 27, wherein said circumferential beads has a height less than that of the screw thread profile of said proximal cylindrical section (11).

25 29. The femur fixture (1) as claimed in claim 27 or 28, wherein the height of said circumferential beads is no greater than 0.3 mm, preferably in the range of 0.1-0.25 mm, and even more preferably approximately 0.2 mm.

30 30. The femur fixture (1) as claimed in any one of the preceding claims, further comprising a head section (5) for supporting a ball component (25) of the hip-joint prosthesis, said head section (5) comprising a collar section (20) having a distal surface (21) abutting said intraosseous anchoring structure (3).

35 31. The femur fixture (1) as claimed in claim 30, wherein said distal surface (21) is inclined inwardly towards the body of the collar section (20).

32. The femur fixture (1) as claimed in claim 31, wherein said distal surface (21) is inclined inwardly at an inclination angle within the range of 10°-20°, preferably approximately 15°.

5 33. The femur fixture (1) as claimed in claim 30, wherein said distal surface (21) is concave.

34. The femur fixture (1) as claimed in any one of claims 30-33, wherein said distal surface (21) is provided with radially spaced circular beads (22).

10 35. The femur fixture (1) as claimed in claim 34, wherein said circular beads have a height in the range of 0.1-0.5 mm, preferably in the range of 0.2-0.4 mm, and even more preferably approximately 0.3 mm.

15 36. A set of femur fixtures according to any one of the preceding claims, wherein the frusto-conical proximal section (18) and the proximal cylindrical section (11) of each fixture (1) in the set have different dimensions, whereby the fixture in the set having the frusto-conical proximal section (18) and the proximal cylindrical section (11) of correct size for abutting the cortex of the
20 femur neck of a particular patient can be selected for use in that patient.

25 37. A set of femur fixtures according to claim 3, wherein the distal cylindrical sections (13) of all fixtures (1) in the set have the same dimension, and the frusto-conical proximal section (18) and the proximal cylindrical section (11) of each fixture (1) in the set have different dimensions, whereby the fixture in the set having the frusto-conical proximal section (18) and the
30 proximal cylindrical section (11) of correct size for abutting the cortex of the femur neck of a particular patient can be selected for use in that patient.

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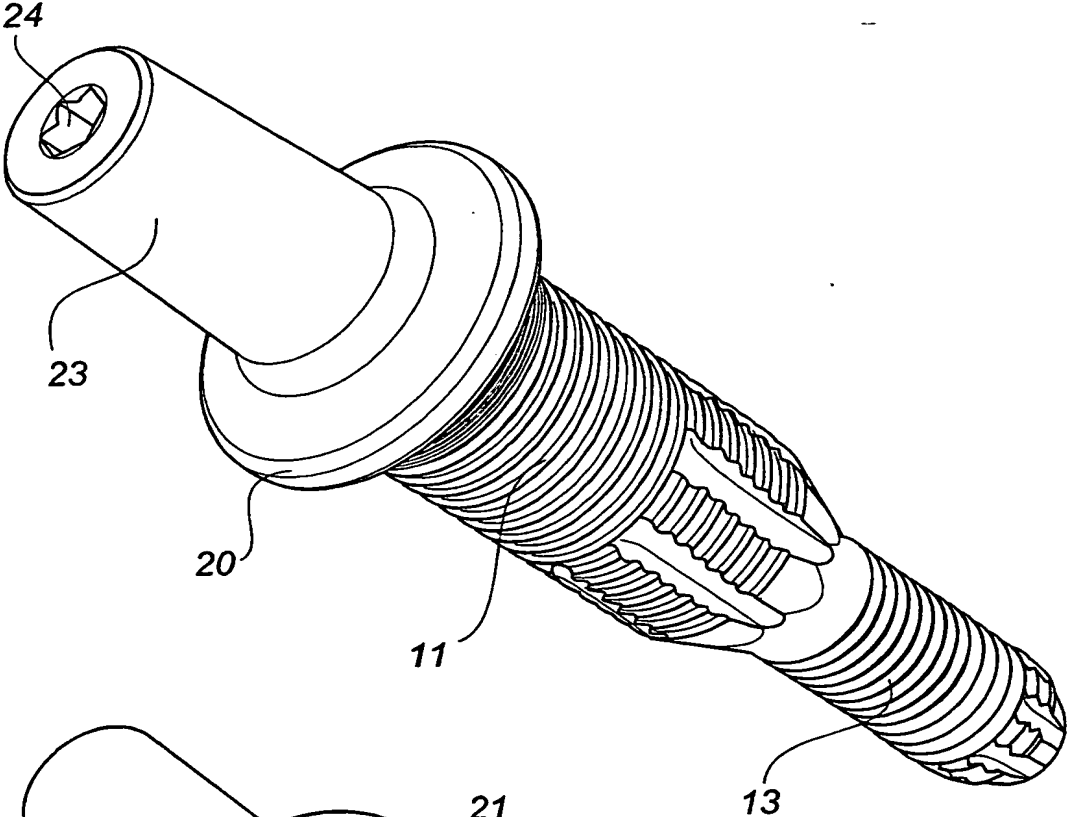


Fig. 1

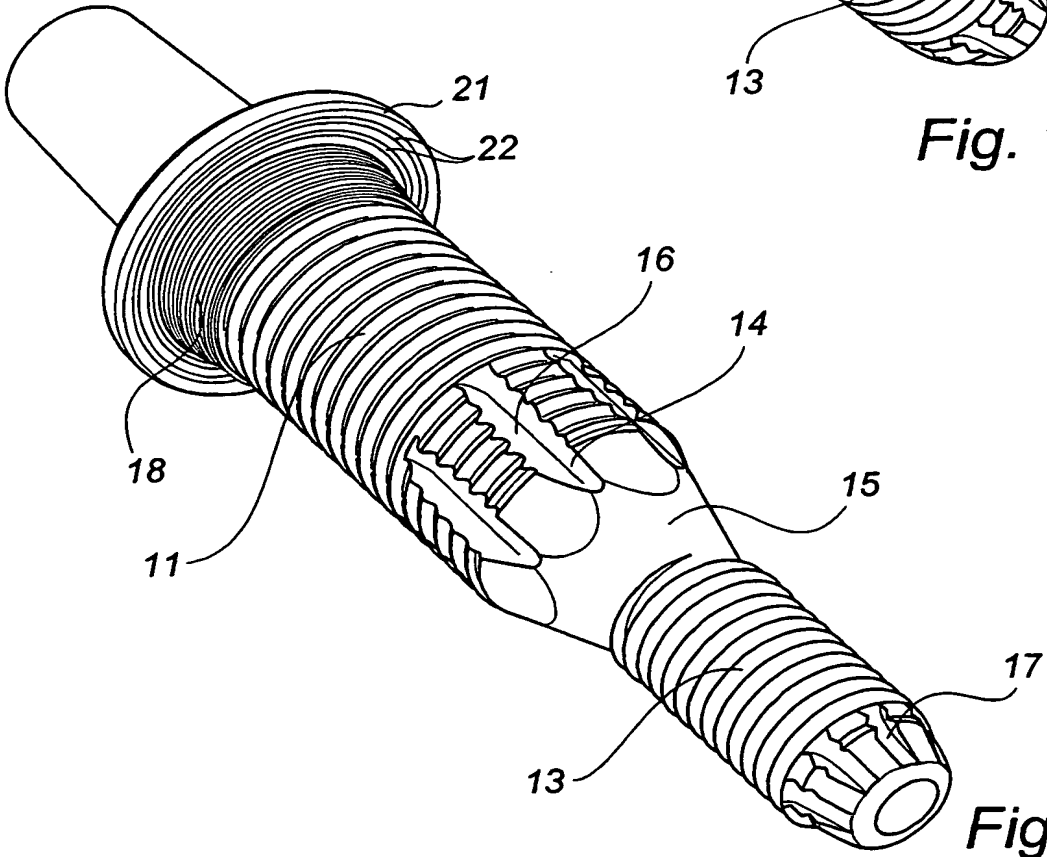
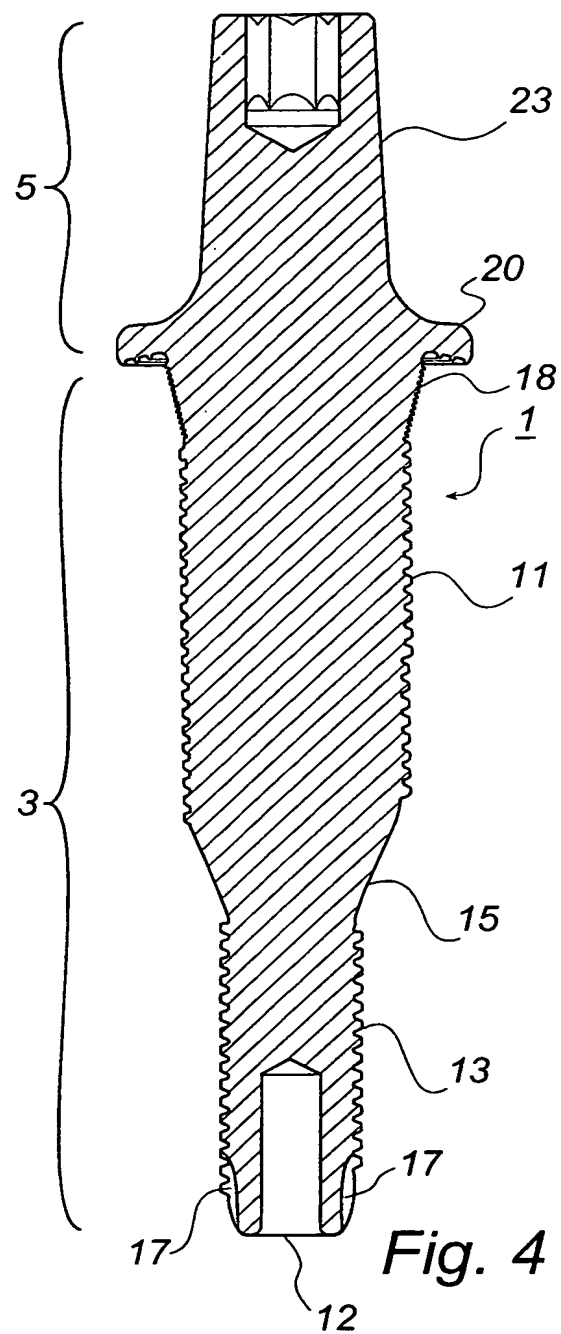
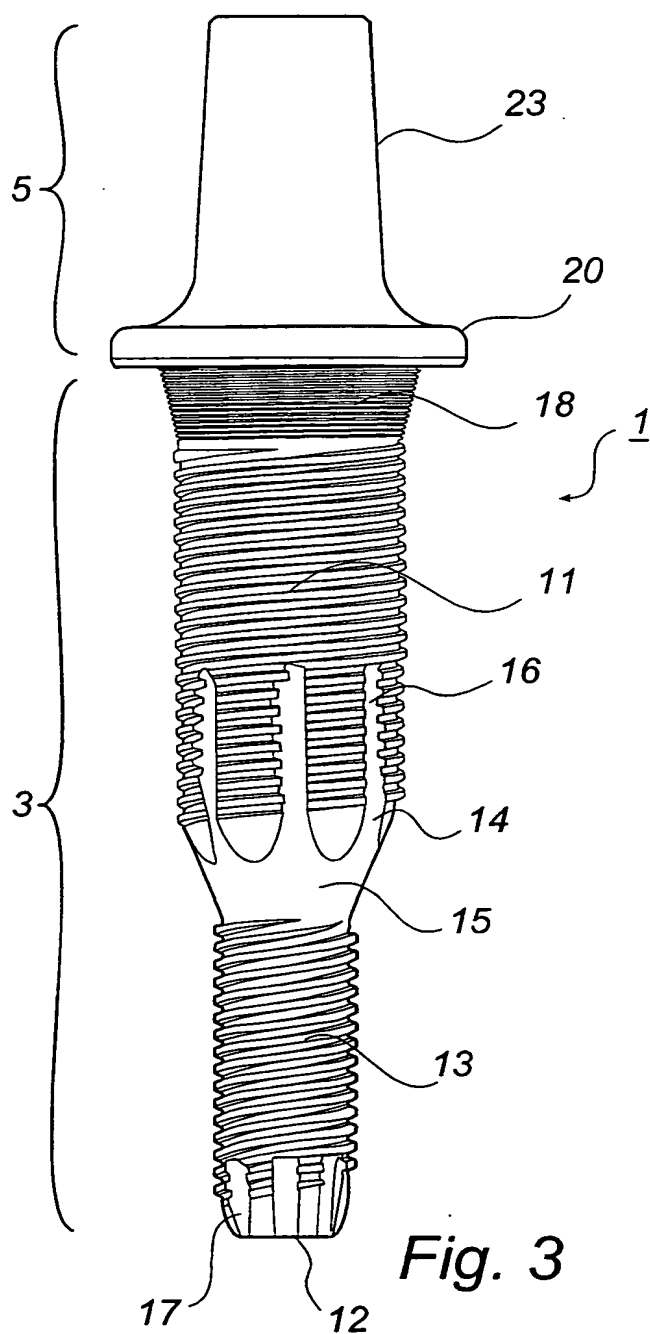


Fig. 2

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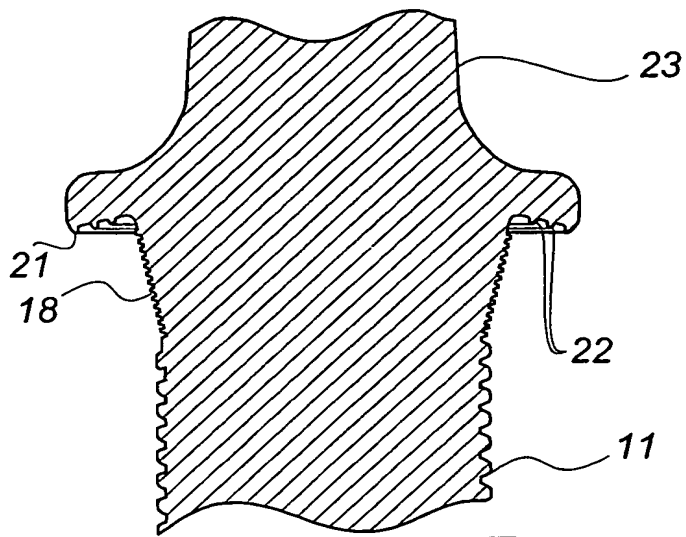


Fig. 5

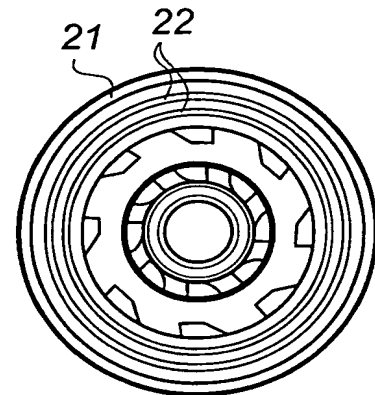


Fig. 6

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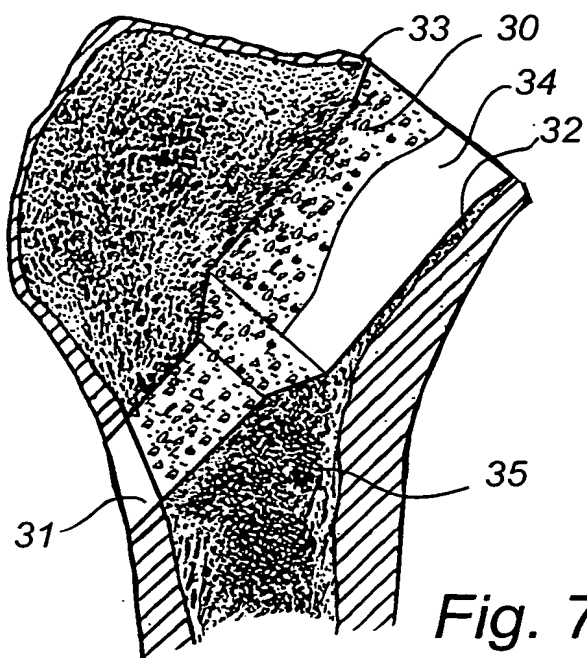


Fig. 7

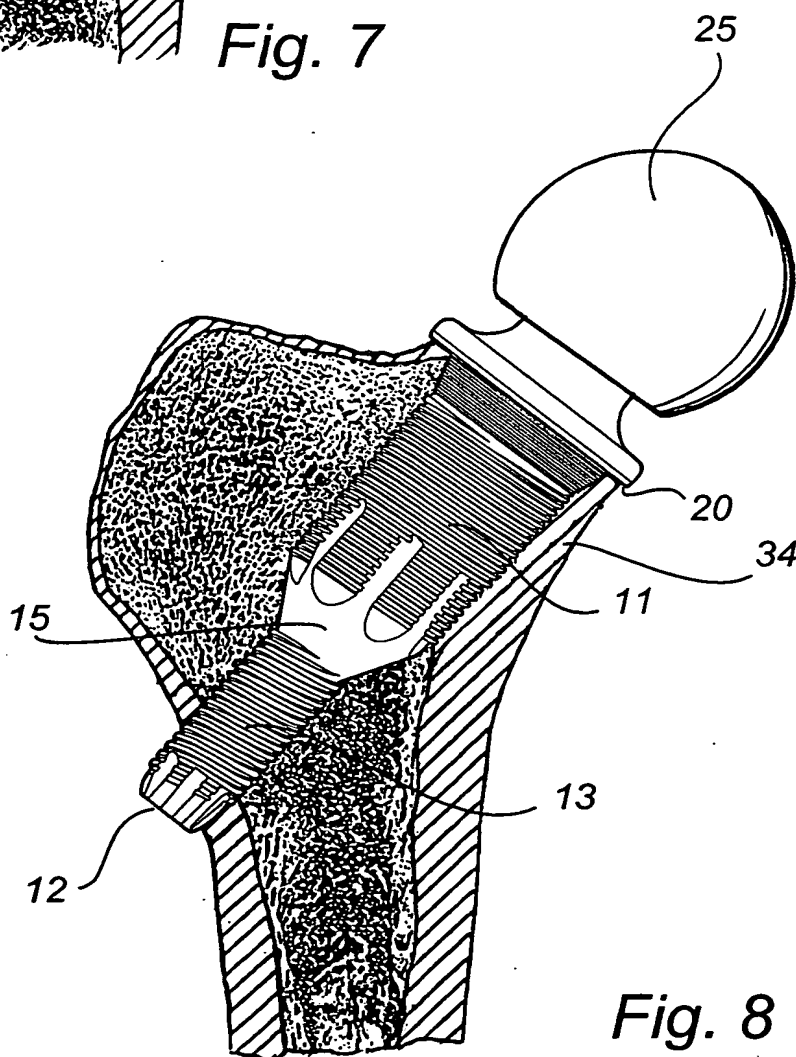


Fig. 8

INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 00/01945

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61F 2/32

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPODOC, MEDLINE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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A	US 3996625 A (NOILES), 14 December 1976 (14.12.76), figure 5 --	1-35
A	US 4051559 A (PIFFERI), 4 October 1977 (04.10.77), column 3, line 52 - column 4, line 2, figure 6 -- -----	1-35

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Further documents are listed in the continuation of Box C.

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See patent family annex.

* Special categories of cited documents:

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Date of the actual completion of the international search

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INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
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